MAYO CLINIC LABORATORIES

Noonan Syndrome and Related Conditions Gene Panel (NSRGG) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Noonan Syndrome and Related Conditions Gene Panel, Varies (NSRGG). To utilize our prior authorization services on this test, you must follow the process as outlined below.

Ordering and Prior Authorization Process

Mayo Clinic Laboratories utilizes an extract and hold process for prior authorization. To order NSRGG with prior authorization services, complete this document as instructed below by insurance type. **You must order test code NSRGG and send the completed paperwork in with the sample**. The receipt of the paperwork and sample at Mayo Clinic Laboratories will trigger the extract and hold process and generate a request to the MCL Business Office to verify your patient's insurance coverage for the testing and begin any additional prior authorization services.

If the expected patient out-of-pocket expense is $200 or less after prior authorization services, Mayo Clinic Laboratories will automatically proceed with NSRGG testing. If the expected patient out-of-pocket expense is greater than $200, Mayo Clinic Laboratories will seek approval from the client contact listed on the Patient Demographics and Third Party Billing Information form **before proceeding** with NSRGG testing. The MCL Business Office offers interest-free payment plans on balances over $200.

Commercial Insurance

For patients with commercial insurance, complete the following, staple them together and send with the specimen:

- Patient Demographics and Third Party Billing Information form (required)
- Letter of Medical Necessity (required)
- Copy of front and back of insurance card (if available)

Note: The Advanced Beneficiary Notice of Noncoverage (ABN) form is not required for commercial insurance-covered patients.

Medicare

For patients with Medicare, complete the following, staple them together and send with the specimen:

- Patient Demographics and Third Party Billing Information form (required)
- Advanced Beneficiary Notice of Noncoverage (ABN) form (required – see separate ABN form: MC2934-339)
- Copy of front and back of secondary insurance card (if applicable)

Attach the ABN form and copy of the secondary insurance card to the Patient Demographics and Third Party Billing Information form and send with the specimen.

Note: The Letter of Medical Necessity and a copy of the Medicare card are not required for Medicare-covered patients.

Medicaid

Mayo Clinic Laboratories may be able to file claims for your Medicaid-covered patients. Before ordering, contact the MCL Business Office at 800-447-6424 to discuss. Have the patient's Medicaid information available when calling.

Note: These instructions are subject to change at any time. Call the MCL Business Office at 800-447-6424 with any questions.

Complete and print.

Reset Form

MAYO CLINIC LABORATORIES

Prior Authorization Patient Demographics and Third Party Billing Information

Client Order Number

Patient Demographics and Insurance Information

Patient Name (Last, First Middle)			Birth Date (mm-dd-yyyy)
Sex Assigned at Birth ☐ Male ☐ Female ☐ Unknown ☐ Choose not to disclose		Legal/Administrative Sex ☐ Male ☐ Female ☐ Nonbinary	
Patient Mailing Address		City	State / ZIP Code
Primary Insurance Company Name	Insurance Subscriber ID No. / Policy No.	Insurance Group No. (if applicable)	
Primary Insurance Company Mailing Address		City	State / ZIP Code
Primary Insurance Company Phone	Subscriber Name (if different than patient) and Relationship to Patient		

Order Information

MCL Test ID **NSRGG**	Name of desired MCL test **Noonan Syndrome and Related Conditions Gene Panel, Varies**
ICD-10 Codes (use number codes to highest specificity)	Service/Collection Date (mm-dd-yyyy)
Referring Provider Name (Last, First)	Referring Provider's National Provider ID (NPI)

Client Account and Client Contact Information

MCL Client Account Number (if known)	Referring Client Facility Name
Contact Name	Contact Phone
Contact Email	Date Today (mm-dd-yyyy)

Attach the Following to This Completed Form

- Letter of Medical Necessity (required except for Medicare patients) – template provided on page 3
- Advanced Beneficiary Notice of Noncoverage (ABN) form (required for Medicare patients only) – see separate form: MC2934-339
  - Templates provided on the following pages
- Copy of front and back of patient's insurance card (if available)

Letter of Medical Necessity for Noonan Syndrome and Related Conditions Gene Panel (NSRGG) Testing

Patient Name (Last, First Middle)

Birth Date (mm-dd-yyyy)

Member Number

Group

ICD-10 Codes

To Whom It May Concern:

We are requesting preauthorization for the Noonan Syndrome and Related Conditions Gene Panel, Varies (NSRGG) performed by

Mayo Clinic Laboratories for (insert patient name)

Patient's personal medical history is significant for

Patient's family history is significant for

Due to the patient's medical history, a diagnosis of Noonan syndrome or a related condition is suspected, and genetic testing is recommended.

Rationale: The use of genetic testing to aid in the diagnosis of Noonan syndrome or a related condition is supported by experts in the field.[1] Identification of a disease-causing variant may assist with diagnosis, prognosis, clinical management, familial screening, and genetic counseling for Noonan syndrome, Noonan syndrome with multiple lentigines, Noonan syndrome with loose anagen hair, cardiofaciocutaneous syndrome, Costello syndrome, Baraitser-Winter syndrome, Legius syndrome, and related conditions. Confirmation of a diagnosis of one of these conditions by molecular genetic testing will directly impact the patient's care.

Noonan syndrome (NS) is an autosomal dominant disorder of variable expressivity characterized by short stature, congenital heart defects, characteristic facial dysmorphology, unusual chest shape, developmental delay of varying degree, cryptorchidism, and coagulation defects, among other features.

Heart defects observed in NS include pulmonary valve stenosis (20%–50%), hypertrophic cardiomyopathy (20%–30%), atrial septal defects (6%–10%), ventricular septal defects (approximately 5%), and patent ductus arteriosus (approximately 3%). Facial features, which tend to change with age, may include hypertelorism, downward-slanting eyes, epicanthal folds, and low-set and posteriorly rotated ears.

The incidence of NS is estimated to be between 1 in 1,000 and 1 in 2,500, although subtle expression in adulthood may cause this number to be an underestimate. NS is genetically heterogeneous, with 4 genes currently associated with the majority of cases: *PTPN11*, *RAF1*, *SOS1*, and *KRAS*. Variants in other genes on this panel have been associated with a smaller percentage of NS and related phenotypes, including Noonan syndrome with multiple lentigines (formerly known as LEOPARD syndrome), Noonan syndrome with loose anagen hair, cardiofaciocutaneous syndrome, Costello syndrome, Baraitser-Winter syndrome, and Legius syndrome.

Genetic testing is used to confirm a diagnosis and/or identify at-risk individuals. This testing would allow for the unequivocal diagnosis of a gene variant causative of the patient's medical history, and would have significant implications for the patient's clinical management regarding decision-making and medical management. For example, identification of a disease-associated variant would confirm a diagnosis of Noonan syndrome or a related condition, and warrant ongoing renal evaluation, periodic cardiac evaluation, coagulation screening, and audiology exams to allow for early intervention before symptoms become severe. Additionally, identification of a disease-associated variant in *PTPN11* or *KRAS* would allow for enhanced screening for these individuals, as they have an increased risk of juvenile myelomonocytic leukemia (JMML) and other malignancies. A positive genetic test result would provide a definitive cause for this patient's medical history and would ensure this patient is being treated appropriately. Furthermore, Noonan syndrome can also present with clinical findings in utero, and has been well-established to be a common cause of increased nuchal translucency in fetuses with normal chromosome analysis.[2] Testing for Noonan syndrome and related conditions can also be performed on samples obtained from prenatal diagnostic procedures if there are prenatal ultrasound findings concerning for Noonan syndrome and related conditions (eg, increased nuchal translucency, polyhydramnios, renal anomalies, distended jugular lymphatic sacs, hydrothorax, cardiac anomalies, cystic hygroma, and/or ascites).

A negative genetic test result could also be informative. A negative result may help to reinforce that the patient does not have Noonan syndrome or related conditions or, alternatively, it could indicate that additional genetic testing (such as whole exome or whole genome sequencing) should be considered to confirm an alternate diagnosis and allow for gene-specific management and screening.

Genetic testing can confirm a diagnosis of heritable Noonan syndrome or related conditions, and a positive result may mean family members are at up to a 50% risk of being affected, or of being a carrier for Noonan syndrome or related conditions. When a familial variant has been identified, genetic testing can identify family members who are not at increased risk to develop Noonan syndrome or related conditions. No other test can reliably differentiate unaffected family members, who do not require further health screening, from presymptomatic affected family members, who must be followed closely by a multi-disciplinary team, including a cardiologist, endocrinologist, geneticist, nephrologist, gastroenterologist, audiologist, ophthalmologist, and other specialists as indicated.

Test requested: Noonan Syndrome and Related Conditions Gene Panel, Varies (NSRGG) is a cost-effective test that utilizes next-generation sequencing (NGS) to evaluate the 20 genes for Noonan syndrome and related condition-associated variants.

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2020 CPT code: 81442.

Thank you for your thoughtful consideration of our preauthorization request. We look forward to hearing back from you.

Sincerely,

Ordering Provider Name

Contact information

References

1. Romano AA, Allanson JE, Dahlgren J, et al. Noonan syndrome: clinical features, diagnosis, and management guidelines. Pediatrics. 2010;126(4):746-759. doi:10.1542/peds.2009-3207
2. Stuurman KE, Joosten M, van der Burgt I, et al. Prenatal ultrasound findings of rasopathies in a cohort of 424 fetuses: update on genetic testing in the NGS era. J Med Genet. 2019;56(10):654-661. doi:10.1136/jmedgenet-2018-105746

Print

MAYO CLINIC LABORATORIES
200 First Street SW
Rochester, Minnesota 55905
800-447-6424

Patient Name (First Middle Last)	MCL Order Number

Advance Beneficiary Notice of Non-coverage (ABN)

Medicare doesn't pay for everything, even some care you or your health care provider think you need. **We expect Medicare may not pay for the item, test, service or care listed below.** If Medicare doesn't pay, you may have to pay.

Item, Test, Service or Care	Reason Medicare May Not Pay	Estimated Cost
NSRGG/Noonan Syndrome and Related Conditions Gene Panel, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$2,600.00

What to do now

- Read this notice to make an informed decision about your care.
- Ask any questions you have.
- Choose one option below to let us know if you still want to get the item, test, service or care.

Choose ONE option below. We can't choose for you.

If you choose Option 1 or 2, we may help you use any other insurance you might have, but Medicare can't require us to do this.

☐ **OPTION 1: I want the item, test, service or care listed above, and I want Medicare to be billed for an official decision on payment, which I'll get on a Medicare Summary Notice (MSN).** You can ask to be paid now. I understand that if Medicare doesn't pay, I'm responsible to pay, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you'll refund any payments I made to you, minus co-pays or deductibles.

☐ **OPTION 2: I want the item, test, service or care listed above, but don't bill Medicare.** You can ask to be paid now and I'm responsible to pay. I understand that I can't appeal, since Medicare isn't billed.

☐ **OPTION 3: I don't want the item, test, service or care listed above.** I understand I'm not responsible for payment and I can't appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. For other questions about this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227). TTY users can call 1-877-486-2048. Signing below means you received and understand this notice. You can ask to get a copy.

Signature ▶	Date (mm-dd-yyyy)

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice.

PRA Disclosure Statement: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. This information collection is for providers, suppliers, Hospice and Religious Non-medical HealthCare Institutes and Home Health Agencies to notify original Medicare beneficiaries of their potential financial liability under specific conditions. The time required to complete this information collection is estimated to average less than 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is mandatory under Section 1879 of the Social Security Act, 42 CFR 411.404(b) and (c) and 411.408(d)(2) and (f). If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.